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SUMMARY

Mexico offers a good market for pharmaceutical products but the current sanitary regulations limit the importation of pharmaceuticals to local manufacturers holding a sanitary license for such products. The estimated value of the Mexican market for pharmaceutical is US \$5 billion. The HS code numbers of the products considered in this estimate are further described in this report.

The private sector holds approximately 80 percent of the total value of the market, but in terms of volume, the public health care sector dispenses the largest number of medicines to the Mexican population. Traditionally, Mexican pharmaceutical firms have had the largest share of the market to the public sector. Approximately, 390 companies --Mexican and multinational-- manufacture pharmaceuticals in Mexico, and about nine percent of them account for almost 80 percent of the total sales. These leading companies are, as in most other countries, the large multinationals.

The private market for generic pharmaceuticals is incipient in Mexico, accounting for less than three percent, and it is expected to grow. However, given the close relationship of these products to political trends, it is difficult to determine how much or how fast will this market grow. Until 1997, the market for generics was limited to the public sector.

The Mexican public health care system is quite different from that of the U.S.; in Mexico, patients under coverage get medical attention and prescriptions at the same place. Public hospitals and clinics have their own pharmacies where patients submit prescriptions. As the number of insured population grows, the demand for low-priced pharmaceuticals increases.

The public health care system provides service to roughly 65 percent of the population. In order to balance the enormous demand for health care services, the Mexican government is trying to have the employed population use their private medical insurance more effectively, in addition to deploy generic pharmaceuticals to the private market.

The U.S. is the largest supplier of pharmaceutical products to the Mexican market. In 2001, the U.S. exported US \$251.13 million to the Mexican market, accounting for 24 percent share of the total import market, and growing 30 percent compared to the previous year. The estimated average annual growth for U.S. exports of pharmaceuticals is 18 percent over the following two years.

Although the North American Free Trade Agreement has either reduced or eliminated import duties for U.S. pharmaceutical products, each member of the agreement still holds the right to establish its own sanitary regulations. For this reason, the condition to have a local manufacturer registering imported pharmaceuticals remains unchanged.

MARKET OVERVIEW

The pharmaceutical industry in Mexico is one of the most developed in Latin America, with a significant local production of bulk active ingredients and finished products. This situation is partially due to the Mexican health regulations, which practically allow only manufacturers to register and therefore import pharmaceutical products into Mexico.

European companies were the first ones to establish local manufacturing facilities, but in the 1970s and early 1980s the number of Mexican pharmaceutical firms increased, as the Government of Mexico (GOM) implemented a policy to substitute imports. Traditionally, Mexican firms have been focused on the manufacture of generic products, for which patents have expired, targeting the public sector as their main customer. Innovative pharmaceuticals are practically limited to multinational companies that transfer the technology from their parent companies.

Over the past 15 years, the GOM has liberalized imports, privatized some industries, and loosened price controls. Although the Mexican pharmaceutical industry is a good example of the new global economy, traces of protectionism still coexist; the GOM still controls the prices of medicines for the private market. Even though the prices of medicines in the private market have increased significantly in the past four years, the average Mexican retail price is about one-fourth to one-third of that in the U.S.

As foreign investment increased, the concern of large multinationals for the lack of adequate intellectual property protection also grew; especially because only chemical processes (not molecules) were patentable. In the late 1980s, the GOM finally changed the law to allow the patentability of chemical molecules for a period of up to 20 years with the possibility to extend 3 more years.

In May 1997, the GOM modified the Mexican Health Law to introduce the concept of "generic pharmaceutical" to the private sector. This new market is known as GI (Genericos Intercambiables - Interchangeable Generics), it must be noted that although generics were already manufactured in Mexico before 1997, this practice was limited to the public sector. When the GI market was created, the private sector openly showed discomfort, mostly because of the questionable enforcement of the protection of intellectual property.

In February 1998, the Mexican health authority (SSA - Secretaria de Salud) released a complementary regulation to clarify some concepts and provide the specifications to identify the products that would be eligible for this market. Periodically, SSA publishes lists of pharmaceuticals that are recommended for the GI group. Later on, SSA releases an official list of the products that were approved and got the sanitary registration as GIs. It is also important to mention that the only case in which the SSA grants two different sanitary registrations to the same product and same manufacturer is the case of branded and GI products. A list of approved GI may be obtained at http://www.ssa.gob.mx/h_medicamentos/gi_medicos.html

Estimates of the total value of the Mexican market for pharmaceutical products in 2001 are US \$7.5 billion. Roughly, the private sector accounts for 80 percent of this total value, and the public sector, 20 percent. In terms of volume, however, this proportion is almost swapped, as

the prices to the public market may well be five times as lower as are those in the private sector. Mexican pharmaceutical firms have the largest share of the market for pharmaceuticals in the public sector.

Under the new administration, the GOM is seeking to relieve the tremendous burden of the public health care system. Latest policies and initiatives for the health care sector focus on the service that patients get at public health care centers; however, the procurement of health care products is also one of the most controversial issues. The need for good quality products at the lowest cost is the puzzle that public institutions have to solve.

MARKET TRENDS

The public health care system provides service to roughly 65 percent of the population, and this has turned it into a mammoth so difficult to operate and administer efficiently. Part of the strategy to divert this burden to the private sector is having the employed population use their private medical insurance more effectively, in addition to deploy generic pharmaceuticals to the private market.

Customarily, Mexican firms have had a minor share of the private market while holding the largest share in the public sector. The inclusion of a private market for generics is just beginning to modify this scenario. Although the market for private generics is currently about three percent of the total market, it has created a new niche for smaller local enterprises which, in some cases, were completely tied to the public sector. Some consumers, however, are still reticent towards the efficacy of these products but for a significant group of people, generics mean an affordable alternative to the frequent product shortage in public institutions.

Unlike the U.S., the Mexican public health care system does not deal with reimbursements; patients under coverage get medical attention and prescriptions at the same place. Public hospitals and clinics have their own pharmacies where patients just need to submit a prescription issued by a physician of the same institution. As the demand for low-priced pharmaceuticals increases, public institutions face a great challenge, which is why the Mexican market for generic products is bound to grow. However, given the close relationship of these products to political trends, it is difficult to determine how much or how fast will this market grow.

In the private market, drugstore chains have taken over the smaller independent ones. Particularly, since supermarket chains started to open full-scale pharmacies within their premises, small neighborhood drugstores have lost their competitiveness and many of them eventually had to shut down. A common practice among some drugstore chains is to offer discounts. Smaller independent drugstores and even some chain retailers go for the full maximum price authorized.

IMPORT MARKET

	PHARMACEUTICALS IMPORT MARKET ^{1/} (US \$ MILLIONS)				
	1999	2000	2001 ^{e/}	2002 ^{f/}	EAAG
IMPORT MARKET	685.07	773.78	1061.98	1260.00	20%

EXPORTS	561.04	400.32	561.04	670.00	
IMPORTS FROM U.S.	162.64	193.20	251.13	295.00	18%

	MP/USD	MP/USD	MP/USD	MP/USD
EXCHANGE RATES ^{2/}	9.56	9.46	9.34	9.52 ^{f/}

1/ Source: Official World Trade Figures, BANCOMEXT (Banco Mexicano de Comercio Exterior - Mexican Foreign Trade Bank)

2/ Year average from data published by BANCO de MEXICO (Mexico's Central Bank)

e/ Estimated.

f/ Forecast.

EAAG: Estimated Average Annual Growth next two years.

Import Market Share
US \$ MILLIONS / %)

COUNTRY	<u>1998</u>		<u>2000</u>	
United States	130.56	23%	251.13	24%
United Kingdom	43.73	8%	108.79	10%
Switzerland	71.38	13%	99.61	9%
Germany	49.84	9%	98.09	9%
France	51.70	9%	90.16	8%
Belgium	27.23	5%	54.87	5%
Puerto Rico	12.19	2%	51.55	5%
Italy	21.96	4%	42.74	4%
Sweden	16.34	3%	29.71	3%
Ireland	10.74	2%	28.80	3%
Colombia	10.11	2%	26.35	2%
Japan	8.15	1%	24.00	2%
Austria	9.85	2%	20.97	2%
Spain	17.29	3%	18.64	2%
Brazil	10.36	2%	18.04	2%
Argentina	8.95	2%	18.03	2%
Netherlands	6.85	1%	16.73	2%
Israel	9.93	2%	14.38	1%

The tables above provide figures for finished allopathic medicines, vaccines and biological products. The total market figure of US \$7.5 billion in 2001 should be looked at carefully, as it often includes not only finished products but also bulk active ingredients and raw materials (commonly known in Mexico as "farmoquimicos"), along with other health care products (e.g. bandages, sutures, diagnostic products, surgical gloves, and other disposable products). Assuming that Mexican exports of pharmaceuticals account roughly for 10 to 15 percent of the local production, the latter may be very estimated in about US \$4.5 billion. Adding local production and imports, and subtracting exports, the total leaner value of the Mexican market would be about US \$5 billion for 2001.

The U.S. is the largest supplier of pharmaceuticals to the Mexican market. In 2000, the U.S. exported US \$193.20 million to the Mexican market, accounting for 25 percent share of the total import market, growing 19 percent compared to 1999. In 2001, the U.S. exported US \$251.13 million to the Mexican market, accounting for 24 percent share of the total import market, and growing 30 percent compared to the previous year.

Among the closest third-country competitors, the UK is the second largest supplier of pharmaceuticals to the Mexican market, accounting for 10 percent share of the total import market, but having a larger share compared to 1998. In 2001 period, the UK exported US \$108.79 million to the Mexican market, accounting for an extraordinary 114 percent growth compared to the previous year. Swiss exports dropped in 1999 and 2000, reaching a bottom US \$53.05 million; however, in 2001, Swiss exports grew by 88 percent. German exports have been growing steadily at an average annual growth of 25 percent reaching US \$98.09 million in 2001. France has shown a trend similar to Germany's. As mentioned earlier, European pharmaceutical companies have been present in Mexico for more than half a century.

COMPETITION

Approximately, 390 laboratories manufacture pharmaceuticals in Mexico, and about nine percent of them account for almost 80 percent of the total sales. Geographically, the pharmaceutical industry is concentrated in the Mexico City metropolitan area, and the states of Morelos, Puebla and Jalisco.

Top 20 Pharmaceutical Companies in Mexico

Roche-Syntex	8.15%
Aventis Pharma	6.15%
Glaxo-Wellcome	3.72%
Novartis	3.27%
Abbott	3.24%
Wyeth	3.11%
Pfizer	2.90%
Boehringer Ingelheim Pharma	2.76%
Bayer	2.76%
Janssen	2.50%
Senosiain	2.47%
Pharmacia Upjohn	2.41%
Merck Sharp & Dohme	2.35%
Eli Lilly	2.24%
SB Farmaceutica	2.09%
BYK Gulden	2.05%
Sanofi-Synthelab	2.01%
Bristol	1.98%
Boehringer Ingelheim OTC	1.96%
Murk	1.83%
Others	40.05%

Source: International Market Service. December, 2001.

Although no single pharmaceutical company holds more than ten percent of the private market, 10 companies account for about 40 percent of the total sales; and 35 companies, reach 80 percent. These leading companies are, as in most other countries, the large multinationals.

The reason why most, if not all, multinational pharmaceutical companies have subsidiaries in Mexico is because, according to the local health regulations, only manufacturers holding a sanitary license can register pharmaceutical products for import and therefore resale in Mexico. In addition, lower wages and free trade agreements with Central America are significant incentives for multinationals to manufacture pharmaceuticals in Mexico.

Health regulations in Mexico are definitely stricter than are those in Central America, but no less strict than are those in the U.S. Considering manufacture and not research and development (R&D), most Mexican pharmaceutical manufacturers are at a world class level. The protectionism of past administrations, back in the 1970s and early 1980s, caused that many Mexican pharmaceutical firms became fully dependent on the public sector. Currently, as the economy has opened, these firms find themselves compelled to improve their productivity in order to be competitive.

In order to protect the general public and promote a lawful competition, the Mexican health authorities have set mandatory standards to ensure the safety, efficacy, and proper labeling of all pharmaceutical products. Whether or not generic, all pharmaceuticals sold to the private market must comply with these Mexican mandatory standards, public institutions apply their own regulations and guidelines.

Apotex, a Canadian pharmaceutical firm established in Mexico in 1996, is a good example of how the market for generic pharmaceuticals is growing. Apotex claims that their total sales in 2001 will account for 500 percent growth compared to 1996. Fifty one percent of their products go to the public sector, 38.5 percent to the private sector, and 10.5 percent to the export market.

Particular to Mexico is a third market of generic pharmaceuticals. Some of the suppliers to the public sector have partially shifted their production to the private market, thus creating another group of generic products known as SIMILARES. These products claim to have the same active ingredients as the original products, but are not subject to comply with the bioavailability tests as formal generics (GIs) are. SIMILARES are neither lawful nor unlawful, they somehow pertain to an ambiguous area in the Mexican legislation. The quality of SIMILARES is subject to compliance with the good manufacturing practices applicable to any pharmaceutical industry, but their interchangeability and dissolution profile are not. This situation has created confusion not only among consumers but also among producers.

For some sectors in the US, Mexico is perceived as a big black market of counterfeit pharmaceuticals. It is important to clarify that those products exist and are indeed dangerous but it is not the case of the whole country. The Mexican border town of Tijuana is perhaps the busiest border crossing in the world, and a large number of people come from all over the US in search of either drugs not yet approved by FDA, or products with much lower prices. According to representatives in the private sector, a town near Tijuana called Algodones has become the destination for these illegal products which, most often, are not even made in Mexico but smuggled from third countries.

END USERS

Public sector

In Mexico, the public sector provides health care services to 60-70 percent of the population, but accounts only for roughly 15 percent of the total value of the market for pharmaceuticals. The main institutions within this sector are, in order of importance:

- IMSS - Mexican Institute of Social Security for private sector employees;
- ISSSTE - The Institute for Social Services and Security for State Employees;
- SSA - Secretariat of Health, for people not covered by other health care institutions;
- Others, such as state government, Red Cross, and other state-owned organizations.

IMSS alone practically holds the public market, although ISSSTE's share is also significant. These institutions can only purchase products --whether or not pharmaceutical-- which are listed in the CUADRO BASICO (basic catalog). This catalog of products is constantly updated, but specifies the exact pharmaceutical form, amount of active ingredient, and number of units per package in which a pharmaceutical product should be presented.

Public institutions may award purchases under US\$3,100 directly to a selected provider, but they must tender purchases valued between US\$3,100 and US\$161,000 and there must be, at least three participants. Purchases over US\$161,000 must be by public tender, whether national or international, and in accordance with NAFTA regulations when applicable. Public tenders are published in the DIARIO OFICIAL DE LA FEDERACION (Mexico's Official Gazette), and in the Internet at www.compranet.gob.mx.

Companies supplying pharmaceutical products to the public sector must comply with a labeling standard different than that for the private sector. It is particularly interesting that although the products which public health care institutions procure have no commercial brand, but only the generic denomination. Nonetheless, these are not obliged to comply with the same bioavailability standards set to the private generic products market (GIs).

IMSS and the SSA used to centralize purchases for all of their health care units nationwide through a purchasing unit in Mexico City. IMSS and SSA are currently turning the procurement over to regional or state administrations. The IMSS has a catalog of products similar to the CUADRO BASICO; an internal committee approves the products that will be included in it. Once again, only products with a valid sanitary registration will be eligible for these catalogs.

Private sector

This sector works much like in the US; multinational firms invest huge sums of money in promoting their products. By law, manufacturers may only advertise ethical products (products sold with a prescription) in specialized publications and among the scientific professionals. Products sold without prescription, commonly known as OTC (over the counter) may be advertised in a much broader way. Readers must note that both categories still need to be registered under the same conditions with the SSA to be sold in Mexico.

The private sector roughly accounts for 85 percent of the total value of the market, but in volume it is the public sector that supplies the vast majority of dosages to the Mexican population. A great difference between the US and Mexican end-users is the control on prescriptions. Self-medication is a common practice in Mexico; many Mexican people do not consult a physician but instead, get "medical" advice from friends, relatives or neighbors. Theoretically, like in the US, OTC products should be the only pharmaceuticals sold without a physician's prescription, but in the practice, pharmacists only require prescriptions if the purchased product contains narcotic substances.

Most insurance programs will only reimburse for medical consultation, treatment, or surgery; very few, however, will do so for prescribed drugs. A significant layer of the Mexican population consider as a second option having a prescription filled at a private pharmacy, if covered by a public health care system.

SALES PROSPECTS

Best sales prospects for pharmaceutical products must be analyzed from different standpoints, as they are the result of numerous external factors that do not follow any particular trend. Many are the factors that U.S. exporters should consider when aiming for the Mexican market.

From a demographic point of view, health concerns change dramatically across Mexico. Rural population has different health problems than metropolitan areas; furthermore, health problems in both groups may vary significantly according to the geographical situation. Southeastern Mexico is mostly warm all year round and very humid, whereas Northern Mexico gets extreme temperatures but is mostly dry. Isolated communities are typically scattered in mountainous regions all across the country where the weather conditions change constantly and health care services are hardly accessible.

Analyzing the Mexican economy, generic pharmaceuticals could be, at first glance, an excellent prospect. However, as mentioned before, the market for generics has long existed in Mexico throughout the public sector, and its transition to the private market has not proven yet fully successful. The Mexican government is still in the process of reviewing different alternatives of health care programs to encompass the adequate use of generics.

MARKET ACCESS

The North American Free Trade Agreement has either reduced or eliminated import duties for U.S. pharmaceutical products. The agreement provides that standards cannot be used as a disguised barrier to trade. NAFTA ensures national treatment and most-favored-nation treatment: goods or specified services from NAFTA countries are treated no less favorably than similar goods from non-NAFTA countries.

Under NAFTA, Mexico, Canada, and the United States have agreed to implement many uniform customs procedures and regulations. The customs provisions benefit U.S. companies by ensuring predictability and transparency in the importing and exporting process. Small-to-medium-sized companies benefit as they often have limited resources to devote to dealing with customs issues. Uniform procedures ensure that exporters who market their product in more than one NAFTA country will not have to adapt to multiple customs regimes.

As of January 1, 2002, NAFTA prescribes that the public health care sector must tender with the U.S. and Canada on purchases over US \$50,000, for official agencies, and US \$250,000 for state-owned companies. NAFTA, however, also allows a general reserve in which the GOM has the liberty to include some products or grant a competitive advantage to local manufacturers.

In addition, each member of the agreement remains sovereign as to maintaining or setting its particular sanitary regulations. In the case of pharmaceuticals, the condition to obtain a sanitary registration is not affected any of above; meaning that only local companies holding a sanitary license for the manufacture of pharmaceuticals are eligible to register such products.

Import Duties and Fees

Heading 3004 of the Harmonized System (HS) includes all pharmaceutical products in measured dosages. The following table includes the HS code under which the majority of pharmaceuticals are classified. Exporters should consult customs brokers to determine the adequate classification. The number on the left shows the duty for non-NAFTA products. The number on the right indicates the duty for NAFTA products effective January 1, 2001.

Tariff Schedule for 2002

HS CODE	ITEM	% RATE	NAFTA
3004.90.99	Other medicines whether or not mixed, intended for therapeutic or prophylactic use, put up in measured dosages or in forms or packaging for retail.	15/1.5	C

The NAFTA code is as follows:

- C Duties shall be removed in 10 equal stages of 10 percent of the NAFTA base rate. This reduction began on January 1, 1994, with full duty elimination on January 1, 2003.

Other subheadings not broken down to the full 8 digits but included in the import and export statistics are:

300210	Antibodies, blood derivatives, modified immunological, included those obtained biotechnologically
300220	Vaccines
300290	Other biological products

Products not dosed or packaged for retail:

3003.10	Antibiotics containing penicillin.
3003.20	Other antibiotics.
3003.31	Products containing insulin.
3003.32	Products containing cortical-suprarenal hormones
3003.39	Products containing hormones or other products listed under heading 2937, but not containing antibiotics.
3003.40	Products containing alkaloids or their derivatives, but not containing hormones, or other products listed under heading 2937, or antibiotics.
3003.50	Products containing vitamins or other products listed under heading 2936.
3003.90	Other medicines whether or not mixed, intended for therapeutic or prophylactic use.

Products dosed or packaged for retail:

3004.10	Antibiotics containing penicillin.
3004.20	Other antibiotics.
3004.31	Products containing insulin.
3004.32	Products containing cortical-suprarenal hormones
3004.39	Products containing hormones or other products listed under heading 2937, but not containing antibiotics.
3004.40	Products containing alkaloids or their derivatives, but not containing hormones, or other products listed under heading 2937, or antibiotics.
3004.50	Products containing vitamins or other products listed under heading 2936.

HS codes are mostly universal, but a few U.S. and Mexican codes are different.

The Import Duty is calculated based on the U.S. plant value (invoice) of the product(s) plus the inland U.S. freight charges to the border, and any other costs listed separately on the invoice and paid by the importer such as export packing. In addition, a customs processing fee (CPF) of 0.8 percent is assessed on the total of the selling price of the product, inland freight cost, other fees (export packaging), plus duty paid and the customs broker fee, if this service is employed. As of July 1, 1999 all products complying with NAFTA rules of origin are not subject to payment of CPF 0.8 percent.

According to modifications in the Mexican customs law, the participation of a customhouse broker is not obligatory for imports if all legal and technical requirements are met. The participation of a customhouse broker is suggested when the exporter is not familiar with the Mexican standards and customs processing procedures.

A 15 percent Value Added Tax (IVA) is then assessed on the cumulative value consisting of the U.S. plant value (invoice) of the product(s), plus the inland U.S. freight charges, any other costs listed separately on the invoice such as export packing plus the duty. The importer will pay other IVA fees for such services as the inland Mexico freight and warehousing. The IVA is recovered at the point of sale.

Imported vs. Domestic Goods

	Non-NAFTA Imported Product	NAFTA Imported Product	Domestic Product
Invoice Value	\$100.00	\$100.00	\$100.00
Ad Valorem Duty	\$15.00	\$3.00	\$0.00
Customs Processing Fee 0.8%	\$0.80	\$0.00	\$0.00
Value Added Tax 15.0%	\$17.37	\$15.45	\$15.00
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Total	\$133.17	\$118.45	\$115.00

In addition, as of April 1, 2002, importers and exporters have to pay 161 pesos per each purchase or sale. This is a flat fee regardless of the number of items per transaction.

Legal requirements:

a) Mexican Official Standards

Compliance with Mexican Official Standards (Normas Oficiales Mexicanas - NOM) is mandatory for all products sold in the Mexican territory. Relevant NOMS that apply to pharmaceuticals are:

NOM-001-SSA1-1993

Original Spanish Title: Norma Oficial Mexicana que instituye el procedimiento por el cual se revisará, actualizará y editará la Farmacopea de los Estados Unidos Mexicanos

Translation: Mexican Official Standard for the procedure to review and edit the Mexican pharmacopoeia.

Published on: June 17, 1994.
In force as of: June 18, 1994.

NOM-073-SSA1-1993

Original Spanish Title: Norma Oficial Mexicana, estabilidad de medicamentos.
Translation: Mexican Official Standard for stability of medicines.
Published on: March 8, 1996.
In force as of: March 9, 1996.

NOM-059-SSA1-1993

Original Spanish Title: Norma Oficial Mexicana, buenas prácticas de fabricación para establecimientos de la industria químico-farmacéutica dedicados a la fabricación de medicamentos.
Translation: Mexican Official Standard for good manufacturing practices of establishments in the pharmaceutical industry that manufacture medicines.
Published on: July 31, 1998.
In force as of: January 31, 1999.

NOM-177-SSA1-1998

Original Spanish Title: Norma Oficial Mexicana que establece las pruebas y procedimientos para demostrar que un medicamento es intercambiable. Requisitos a que deben sujetarse los terceros autorizados que realicen las pruebas.
Translation: Mexican Official Standard for tests and procedures to prove that a medicine is interchangeable. Requirements that authorized third parties must comply.
Published on: May 7, 1999.
In force as of: May 8, 1999.

NOM-176-SSA1-1998

Original Spanish Title: Norma Oficial Mexicana, requisitos sanitarios que deben cumplir los fabricantes, distribuidores y proveedores de fármacos utilizados en la elaboración de medicamentos de uso humano
Translation: Mexican Official Standard, sanitary requirements for manufacturers, distributors, and suppliers of pharmaceuticals used in the preparation of medicines for human use.
Published on: December 17, 2001.
In force as of: January 17, 2002.

b) Labeling

NOM-072-SSA1-1993

Original Spanish Title: Norma Oficial Mexicana, etiquetado de medicamentos.
Translation: Mexican Official Standard for labeling of medicines.
Published on: April 10, 2000.
In force as of: October 10, 2000.

A copy of these, and all Mexican standards, can be downloaded from the web page of the General Directorate of Standards at www.economia-noms.gob.mx

c) Sanitary Registration

In addition to Official Standards, pharmaceutical products such as active ingredients, finished medicines in bulk, and finished medicines in retail packages, must be registered with the SSA. Only local companies holding a sanitary license for the manufacture of pharmaceuticals are eligible to register such products. This registration is only for sanitary purposes only; the intellectual property protection is a separate process with a different government agency.

The fact that a product has been FDA approved does not exempt it from the requirement of the SSA registration. FDA approval does, however, help speed up the process to obtain the SSA registration. Products not yet approved by FDA will be subject to perform clinical trials within Mexico; clinical trials performed elsewhere will have no validity.

For more details on the sanitary registration please review the document titled Registration of Allopathic Pharmaceuticals published by the U.S. Commercial Service under the series International Market Insights.

d) Import Permit

Once the product has obtained a sanitary registration code, the importer must file an import permit application with the SSA to have access to the Mexican territory. Only in some cases such as personal use or research, are product exempted from being registered.

For more information on sanitary permits, licenses, and registration please check:
www.salud.gob.mx/unidades/dgcis/

Certificate of Origin

Products qualifying as North American under NAFTA must use the NAFTA Certificate of Origin to receive NAFTA beneficial treatment. This certificate may be issued by the exporter or freight forwarder and does not have to be validated or formalized.

Only North American products, as defined by the rules of origin, are eligible for preferential tariff treatment. In general, 51 percent or more NAFTA content by value is required to get a NAFTA Certificate of Origin.

The U.S. Commerce Department's NAFTA Office assists U.S. exporters to take advantage of trade opportunities in Canadian and Mexican markets within the framework of the Agreement.

For additional counseling and help on exporting, please contact the following:

1-800-USA-TRADE (1-800-872-8723)
<http://www.export.gov>